K003695

510(k) SUMMARY

FEB 1 4 2001

The Summary of Safety and Effectiveness on the Family of MicroScopes reflects data available and represented at the time the submission was prepared, but caution should be exercised in interpreting the data. The results of future studies may require alterations of the conclusions or recommendations set forth.

Applicant	George Coleman, General Manager Micro Medical Devices, Inc. 11000 Cedar Avenue Cleveland, OH 44106
Telephone	216/229-8332
Facsimile	216/229-8348
Date	November 29, 2000
Name	Family of MicroScopes
Classification	Arthroscopes and accessories, 21 CFR 888.1100
Predicate:	K934707 Galileo Arthroscope, market clearance date October 7, 1994
Description	The Family of MicroScope consists of a fiber optical image train and a fiber optic illumination train built into stainless steel tube assembly. Two model ranges are based upon the diameter of the MicroScope, and each model has the option to configure the angle of the lens (0°, 25°, 60°) and the length (5cm through 45cm). The device does not contain any electrical capabilities. The light from the light source is transmitted to and through the endoscope using fiber optics.
Intended Use	MicroScope is intended for insertion into a small incision or puncture (through a cannula) to view the surgical site of small and large joints of the wrists, ankles, elbows, knees, or shoulders in conjunction with cameras.
Contraindications	Bending or prying with scope will damage optics.
Caution	Federal law (U.S.A.) restricts this device to sale by or on the order of a physician.
Technological Characteristics	There are no published standards for these particular types of products, and as such tests have been developed which are considered sufficient to ensure the efficacy and safety of the device(s) for its intended use. Such tests include - Visual; Thermal; Functional and Dimensional.
Data Submitted	The biological safety assessment of the MicroScope has been performed in accordance with the International Standard ISO 10993, Part 1:1994, "Biological Evaluation of Medical Devices: Evaluation and Testing."

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 1 4 2001

Mr. George Coleman
General Manager
Micro Medical Devices, Inc.
11000Cedar Avenue
Suite 445
Cleveland, Ohio 44106

Re: K003695
Trade Name: Microscope/Fiber Optic 5-2.6mm Model
Regulatory Class: II
Product Code: HRX
Dated: November 29, 2000
Received: November 30, 2000

Dear Mr. Coleman:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Miriam C Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K003695

Device Name: Family of MicroScope

Indications For Use:

MicroScope is intended for insertion into a small incision or puncture (through a cannula) to view the surgical site of small and large joints of the wrists, ankles, elbows, knees, or shoulders in conjunction with cameras.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C Provost

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K003695

Prescription Use ✓ OR Over-The-Counter-Use _____
(Per 21 CFR 01.109)

(Optional Format 1-2-96)

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